

September 17, 2013

Document Processing Desk (DCI/AD) Attn: Reevaluation Team Leader, PM36 U.S. EPA (7510P) One Potomac Yard (South Building) 2777 S. Crystal Dr. Arlington, VA 22202

Attn: Wanda Henson

Subject:

Bronopol Generic Data Call In 90-day response

Registrant: Thor GmbH, U.S. Agent: Thor Specialties, Inc., Company No. 67071

In accord with item C, Satisfying the Data Requirements of this Notice, Thor has acknowledged on the Attachment B, Generic Data Call In Response Forms that they agree to satisfy the data requirements and selected Option 3, Offer to Share in the Cost of Data Development (forms attached). As stated in the DCI

"EPA has determined that as a general policy, . . . it will not suspend the registration of a product(s) of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer."

Thor is attaching copies of their offers to all other known bronopol companies (3) who are responsible for generating the requested data along with copies of the blatant rejections from all 3 companies refusing to allow Thor to share in the burden of developing the requested data. Also, in accord with Option 3, Thor is attaching a completed EPA Form Certification of Attempt to Enter into an Agreement with Registrants for Development of Data identifying the companies to whom attempts to enter into an agreement were sent.

Thor was informed that these 3 companies were the only companies who would not be eligible for a generic exemption. Also, Lanxess acknowledge that Dow, BASF and Lanxess are the only companies in the data sharing agreement.

In accord with the DCI instructions attached is a completed Data Call In Response form indicating that Thor is agreeing to satisfy the applicable generic Data Requirements on the "Requirements Status and Registrants Response Form" for their 8 products containing bronopol. Also attached is the Requirements Status and Registrant's Response form indicating in column 9 that Thor's response is Response Code 3 supported by the attached attempts to cost share, plus the completed "Certification of Attempt to Enter into an Agreement with Registrants for Development of Data".

Email: info@thorsp.com



Document Processing Desk (DCI/AD) Reevaluation Team Leader, PM36 Bronopol Generic Data Call In 90-day response Page 2 of 2

If you have any questions about our response or the material provided, please do not hesitate to contact me.

Sincerely,

Lynn P. Tordo, M.S. Regulatory Manager

Lyn P. Zordo

Attachments: Attachment A -- Data Call-In Response Form (cover + 1 page)

Attachment B -- Requirements Status and Registrants Response (cover + 3 pages) Attachment C -- Certification of Attempt to Enter into an Agreement with Registrants

for Development of Data (cover + 1 page)

Attachment D -- Copies of offer to other registrants along with rejections (cover + 6 pages)

Geri Werdig, Pesticide Registration Associates, D.C. cc:

Email: info@thorsp.com

## ATTACHMENT A

Data Call-In Response Form

Bronopol 216400

# United States Environmental Protection Agency Washington, D.C. 20460

OMB Approval 2070-0174

DATA CALL-IN RESPONSE							Olvid Approval 2070-0174	
INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.  Use additional sheet(s) if necessary.								
1. Company Name and Address THOR GMBH 50 WATERVIEW DRIVE SHELTON, CT 06484			2. Case # and Name 2770 - Bronopol Chemical # and Name Bronopol	: 216400	3. Date and Type of DCl and Number 02-Jul-2013 GENERIC ID # GDCl-216400-1336			
4. EPA Product	5. I wish to cancel	6. Generic Data			7. Produ	7. Product Specific Data		
Registration	this product registration voluntarily	6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.		6b. I agree to satisfy Generic Data Requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirement on the attached form entitled "Requirements Status and Registrant's Response."		7b. My product is an EUP and I agree to satisfy the EUP requirement on the attached form entitled "Requirements Status and Registrant's Response."	
67071-16				Х	NA		N/A	
67071-18				Х	N/A		N/A	
67071-45				Х	N/A		N/A	
67071-46				X		N/A	N/A	
67071-50				Х	NA		N/A	
67071-68				Х		N/A	N/A	
67071-75				Х	N/A		N/A	
67071-76				X		N/A	N/A	
know ingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.							Date	
							Sept. 17,2013	
10. Name of Company Thor Specialties, Inc. US Agent for Thor GmbH							1. Phone Number 203-516-6980	

## ATTACHMENT B

Requirements Status and Registrants Response

Bronopol

216400

## United States Environmental Protection Agency Washington, D.C. 20460

## REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.										
1. Company Name and Address		2. Case # and Name						3. Date and Type of DCI and Number		
THOR GMBH 50 WATERVIEW DRIVE SHELTON, CT 06484		2770 - Bronopol Chemical # and Name: 216400 Bronopol			02-Jul-2013 GENERIC ID # GDCl-216400-1336					
Guideline Requirement Number	5. Study Title				Progre Repo		6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			O L	1	2	3				
	Applicator Exposure Data Requirement Chemical)	nts (Conventional								
875.1700	Product Use Information		N		1		T,K,Y,F,EE,X,Z	TGAI	12	3
	Nontarget Plant Protection Data Requ Chemical)	irements (Conventional								
850.5400	Algal toxicity, Tiers 1 and II	(4)	N				T,K,Y,F,EE,X,Z	TGAI	12	3
	Post-Application Exposure Data Required Chemical)	irements (Conventional								
875.2800	Description of human activity		Ν				T,K,Y,F,EE,X,Z	TGAI	12	3
835.3110	Ready biodegradability	(7)	Ν				T,K,Y,F,EE,X,Z	TGAI	12	3
835.3220	Porous pot test	(7)	N		ı		T,K,Y,F,EE,X,Z	TGAI	12	3
835.3240		(7)	Ν		l		T,K,Y,F,EE,X,Z	TGAI	12	3
10. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.										
Signature and Title of Company's Authorized Representative Zyn P. Torslo Regulatory Manager Sept. 17, 2013										
12. Name of Company Thor Specialties, Inc. US Agent for Thor GmbH 13. Phone Number 203-516-6980										

## United States Environmental Protection Agency Washington, D.C. 20460

## REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary. 1. Company Name and Address 2. Case # and Name 3. Date and Type of DCI and Number 02-Jul-2013 THOR GMBH 2770 - Bronopol 50 WATERVIEW DRIVE Chemical # and Name: 216400 GENERIC Bronopol ID # GDCI-216400-1336 SHELTON, CT 06484 8. Time 4. Guideline 6. Use 7. Test 9. Registrant 5. Study Title Progress R Frame Response Requirement Reports Pattern Substance Number 0 (Months) T 0 C 0 2 1 3 Simulation Test-Aerobic Sew age Treatment-Activated Sludge 3 835.3280 Simulation Tests to Assess the Biodegradability of T,K,Y,F,EE,X,Z TGAI 12 (7)Chemicals 3 T,K,Y,F,EE,X,ZTGAI 12 850.1300 Daphnid chronic toxicity test 3 TGAI 12 Fish early-life stage toxicity test T,K,Y,F,EE,X,Z 850.1400 3 12 850.4225 Seedling emergence, Tier II T,K,Y,F,EE,X,Z TGAI 3 850.4250 Vegetative vigor, Tier II T,K,Y,F,EE,X,Z TGAI 12 3 850.4400 Aquatic plant toxicity test using Lemna spp. Tiers I T,K,Y,F,EE,X,Z TGAI 12 and II 3 T,K,Y,F,EE,X,ZModified Activated Sludge Respiration Inhibition TGA! 12 850.6800 (6)T,K,Y,F,EE,X,Z 24 3 TGAL 870.3465 90-day inhalation toxicity

## United States Environmental Protection Agency Washington, D.C. 20460

OMB Approval 2070-0174

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary. 1. Company Name and Address 2. Case # and Name 3. Date and Type of DCI and Number 02-Jul-2013 THOR GMBH 2770 - Bronopol 50 WATERVIEW DRIVE Chemical # and Name: 216400 GENERIC ID # GDCI-216400-1336 SHELTON, CT 06484 Bronopol 7. Test 8. Time 9. Registrant 4. Guideline 6. Use 5. Study Title Progress Requirement R Reports Pattern Substance Frame Response Number 0 (Months) T 0 C 0 1 2 3 3 875.1100 T,K,Y,F,EE,X,Z TGAI 12 Dermal exposure--outdoor (3, 5)3 TGAI 12 875.1200 Dermal exposure--Indoor T,K,Y,F,EE,X,Z (3, 5)3 T,K,Y,F,EE,X,Z TGAI 12 875.1300 Inhalation exposure--outdoor (2, 5)875.1400 Inhalation exposure--indoor (1, 2, 5)T,K,Y,F,EE,X,Z TGAI 12 3 3 875.2700 Product Use Information T,K,Y,F,EE,X,Z TGAI 12

## ATTACHMENT C

Certification of Attempt to Enter into an Agreement with Registrants for Development of Data

Bronopol 216400



# United States Environmental Protection Agency Washington, D.C. 20460 CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH REGISTRANTS FOR DEVELOPMENT OF DATA

Form Approved.

OMB Nos. 2070-0057; 2070-0107; 2070-0122; 2070-0164

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 15 minutes per response including time for reading the instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

Please fill in blanks below				
Company Name	Company Number			
Thor GmbH	67071			
Chemical Name	EPA Chemical Number			
Bronopol	216400			
I Certify that:				
My company is willing to develop and submit the data	a required by EPA under the authority of the Federal Insecticide,			

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Rodenticide and Fungicide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer
The Dow Chemical Company	July 22, 2013
BASF Corporation	July 22, 2013
Lanxess Corporation	July 22, 2013

## Certification:

I certify that I am duly authorized to represent the company name above, and that the statements that I have made on this form and all attachments therein are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Lyn P. Torde	Sept. 17, 2013

Name and Title (Please Print or Type)

Lynn P. Tordo, Regulatory Manager Thor Specialties, Inc. (US Agent for Thor GmbH)

## ATTACHMENT D

Copies of Offer to Other Registrants Copies of Rejections to Offer

> Bronopol 216400



July 22, 2013

Luanne Jeram LANXESS Corporation Material Protection Products 111 RIDC Park West Drive Pittsburgh, PA 15275-1112

Re: Bronopol DCI

Effort to Identify Source(s) or Availability of Data to Comply with Bronopol DCI (Option 2)

### Dear Luanne,

Like your company, we received the Bronopol DCI. Thor does not currently have access to the all the required data nor are we currently generating this data. Due to the amount of data being required and the resulting potential data costs and in accord with Option 2 in the DCI, Thor is seeking information on an agreement to share in the cost of producing the required data and/or an agreement to share the costs of data already generated.

Information available to us indicates that your company may have access to part or all of the data to fulfill the requirements of the Bronopol DCI and that consequently, you would be willing to submit the data to EPA and to participate in a data-sharing agreement. If this information is not correct, please provide whatever information or guidance you may have on this subject. Alternately, Thor is currently interested in participating with you in the generation of studies to comply with this DCI.

If the addressee is not the proper person in your organization to address this effort, please forward this letter to them and inform us who it is. I am the contact for Thor, so please address all responses to my attention.

Thor will be looking forward to receiving your response regarding your availability of data to fulfill the Bronopol DCI.

Sincerely,

Lynn P. Tordo, M.S. Regulatory /QA Manager

Lyn P. Tordo

Rec'd 2013



Luanne Jeram Material Protection Products 111 RIDC Park West Drive Pittsburgh, PA 15275-1112

Phone 412-809-4773 Fax 412-809-1068 Luanne.jeram@lanxess.com www.US.LANXESS.com

August 14, 2013

Ms. Lynn P. Tordo Thor Specialties, Inc. 50 Waterview Drive Shelton, CT 06484

Re:

Bronopol Data Call-In

Request to Participate in Data- Sharing (Option 2)

Dear Ms. Tordo:

Your letter dated July 22, 2013 requesting to enter into a data-sharing agreement with LANXESS Corporation in development of data for the Bronopol Data Call-In (DCI) has been reviewed by our company.

Unfortunately, due to an already existing global data sharing agreement amongst Dow, BASF and LANXESS, we are unable to honor your request.

Please feel free to contact us if you have any questions.

Sincerely,

Luanne Jeram

Head, Regulatory Affairs, MPP NA

LANXESS Corporation

Via certified mail



July 22, 2013

Abigail Trueblood Product Stewardship Regulatory Manager Dow Microbial Control THE DOW CHEMICAL COMPANY 1500 East Lake Cook Road Buffalo Grove, IL 60089

Re: Bronopol DCI

Effort to Identify Source(s) or Availability of Data to Comply with Bronopol DCI (Option 2)

## Dear Abby,

Like your company, we received the Bronopol DCI. Thor does not currently have access to the all the required data nor are we currently generating this data. Due to the amount of data being required and the resulting potential data costs and in accord with Option 2 in the DCI, Thor is seeking information on an agreement to share in the cost of producing the required data and/or an agreement to share the costs of data already generated.

Information available to us indicates that your company may have access to part or all of the data to fulfill the requirements of the Bronopol DCI and that consequently, you would be willing to submit the data to EPA and to participate in a data-sharing agreement. If this information is not correct, please provide whatever information or guidance you may have on this subject. Alternately, Thor is currently interested in participating with you in the generation of studies to comply with this DCI.

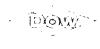
If the addressee is not the proper person in your organization to address this effort, please forward this letter to them and inform us who it is. I am the contact for Thor, so please address all responses to my attention.

Thor will be looking forward to receiving your response regarding your availability of data to fulfill the Bronopol DCI.

Sincerely,

Lynn P. Tordo, M.S. Regulatory /QA Manager

Tyn P. Torde



The Dow Chemical Company 1500 E. Lake Cook Road Buffalo Grove, IL 60089

August 14, 2013

Peold 12013 8/19/2013

Ms. Lynn P. Tordo Thor Specialties, Inc. 50 Waterview Drive Shelton, CT 06484

Re:

Bronopol Data Call-In

Request to Participate in Data-Sharing (Option 2)

Dear Ms. Tordo:

Your letter dated July 22, 2013 requesting to enter into a data-sharing agreement with The Dow Chemical Company (Dow) in development of data for the Bronopol Data Call-In (DCI) has been reviewed by our company.

Unfortunately, due to an already existing global data sharing agreement amongst Dow, BASF and LANXESS, we are unable to honor your request.

Please feel free to contact us if you have any questions.

Sincerely,

Abigail Trueblood

Product Stewardship Regulatory Manager

**Dow Microbial Control** 

The Dow Chemical Company

March Turkon



July 22, 2013

J.K. Delahay Sr. Product Regulatory Specialist BASF 100 Park Ave. Florham Park, NJ 07932

Re: Bronopol DCI

Effort to Identify Source(s) or Availability of Data to Comply with Bronopol DCI (Option 2)

Dear J.K.,

Like your company, we received the Bronopol DCI. Thor does not currently have access to the all the required data nor are we currently generating this data. Due to the amount of data being required and the resulting potential data costs and in accord with Option 2 in the DCI, Thor is seeking information on an agreement to share in the cost of producing the required data and/or an agreement to share the costs of data already generated.

Information available to us indicates that your company may have access to part or all of the data to fulfill the requirements of the Bronopol DCI and that consequently, you would be willing to submit the data to EPA and to participate in a data-sharing agreement. If this information is not correct, please provide whatever information or guidance you may have on this subject. Alternately, Thor is currently interested in participating with you in the generation of studies to comply with this DCI.

If the addressee is not the proper person in your organization to address this effort, please forward this letter to them and inform us who it is. I am the contact for Thor, so please address all responses to my attention.

Thor will be looking forward to receiving your response regarding your availability of data to fulfill the Bronopol DCI.

Sincerely.

Lynn P. Tordo, M.S. Regulatory /QA Manager

Lyn P. Torako



## Helping Make Products Better™

August 15, 2013

· Pecid 2013

Ms. Lynn P. Tordo Thor Specialties, Inc. 50 Waterview Drive Shelton, CT 06484

Re: Bronopol Data Call-In

Request to Participate in Data- Sharing (Option 2)

Dear Ms. Tordo:

Your letter dated July 22, 2013 requesting to enter into a data-sharing agreement with, BASF Corporation in development of data for the Bronopol Data Call-In (DCI) has been reviewed by our company.

Unfortunately, due to an already existing global data sharing agreement amongst Dow, BASF and LANXESS, we are unable to honor your request.

Please feel free to contact us if you have any questions.

Sincerely,

J.K. Delahay

Sr. Product Regulatory Specialist Care Chemicals, North America

Phone: 1 973 245-7614 Mobile: +1 973-282-6543

E-Mail: james.delahay@basf.com

Postal Address:

BASF Corporation, 100 Park Avenue, Florham Park NJ 07932

cc: M. Paquette, BASF